

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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| Applicant's or agent's file reference: 30067 | | Date of mailing (day/month/year) 30 NOV 2006 FOR FURTHER ACTION See paragraph 2 below |
| International application No. PCT/IL05/00589 | International filing date (day/month/year) 05 June 2005 (05.06.2005) | Priority date (day/month/year) 02 August 2004 (02.08.2004) |
| International Patent Classification (IPC) or both national classification and IPC IPC: A61K 38/00(2006.01) USPC: 514/12 | | |
| Applicant RAMOT AT TEL AVIV UNIVERSITY LTD | | |

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | Date of completion of this opinion 19 September 2006 (19.09.2006) | Authorized officer Marcela M. Cordero Garcia Telephone No. (571) 272-1600 |
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Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL05/00589

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-----------------------|-----|
| Novelty (N) | Claims <u>2, 4-64</u> | YES |
| | Claims <u>1, 3</u> | NO |
| Inventive step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-64</u> | NO |
| Industrial applicability (IA) | Claims <u>1-64</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Claims 1 and 3 lack novelty under PCT Article 33(2) as being anticipated by Lazaris et al. (Science, 2002). Lazaris et al. teach a method of forming a fiber made of peptide nanostructures, the method comprising providing peptide nanostructures in solution, and fiberizing said solution thereby forming at least one fiber of said peptide nanostructures. (See, e.g., Lazaris, pages 474-475). Therefore the reference anticipates the instant claims.

Claims 2, 4-8 lack an inventive step under PCT Article 33(3) as being obvious over Lazaris et al. (Science, 2002). Lazaris et al. teach a method of forming a fiber made of peptide nanostructures, the method comprising providing peptide nanostructures in solution, and fiberizing said solution thereby forming at least one fiber of said peptide nanostructures. (e.g., pages 474-475). Lazaris et al. do not expressly teach e.g., dry spinning. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lazaris et al. by varying the type of spinning used. One of skill in the art would have been motivated to do so since Lazaris et al. teach that by varying the spinning parameters, fibers with a range of specifications can be produced (page 475, column 3, lines 32-44). Therefore the invention as a whole is clearly prima facie obvious over the reference.

Claims 9-64 lack an inventive step under PCT Article 33(3) as being obvious over Haynie (US 2005/00699950 A1). Haynie teaches a method of forming a film of peptide nanostructures. Haynie does not expressly teach incubating an organic solution in order to make a peptide film. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Haynie by utilizing organic solvent crystallization. One of skill in the art would have been motivated to do so since depositing/crystallization from incubation in a solvent is well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such method of forming films of peptide nanostructures (e.g., selecting repeating units, substituting and functionalizing amino acid chains, and so forth) based upon the overall beneficial teachings provided by Haynie. These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. Therefore the invention as a whole is clearly prima facie obvious over the reference.

Claims 1-64 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL05/00589

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments: